THIS OPINION WAS NOT WRITTEN FOR PUBLICATION

The opinion in support of the decision being entered today (1) was not written for publication in a law journal and (2) is not binding precedent of the Board.

Paper No. 24

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte PAUL J. BUSCEMI

Appeal No. 97-2552
Application No. 08/541,658[1]

ON BRIEF

Before CALVERT, ABRAMS, and NASE, Administrative Patent Judges.

NASE, Administrative Patent Judge.

DECISION ON APPEAL

This is a decision on appeal from the examiner's final rejection of claims 3 through 8. Claims 1, 2 and 9 through 18 have been allowed.

We REVERSE and enter a new rejection pursuant to 37 CFR

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[1] Application for patent filed October 2, 1995. According to the appellant, the application is a continuation of Application No. 08/134,978, filed October 12, 1993, now abandoned.

§ 1.196(b).

BACKGROUND

The appellant's invention relates to a catheter. An understanding of the invention can be derived from a reading of exemplary claim 3, which appears in the appendix to the appellant's brief.

The prior art references of record relied upon by the examiner in rejecting the appealed claims are:

Gottschalk et al. (Gottschalk)	5,035,621	July 30, 1991
Levy	5,092,773	March 3, 1992
Thomas	5,184,044	Feb. 2, 1993

References made of record by this panel of the Board are:

Sinofsky (Sinofsky '670)	5,207,670	May 4, 1993
Sinofsky (Sinofsky '677)	5,540,677	July 30, 1996[2]

Claims 3, 4, 5 and 8 stand rejected under 35 U.S.C. § 103 as being unpatentable over Levy in view of Thomas.

Claims 6 and 7 stand rejected under 35 U.S.C. § 103 as being unpatentable over Levy in view of Thomas and Gottschalk.

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[2] This patent has an effective filing date under 35 U.S.C. § 102(e) of May 3, 1993.

Rather than reiterate the conflicting viewpoints advanced by the examiner and the appellant regarding the above-noted rejections, we make reference to the final rejection (Paper No. 15, mailed August 8, 1996) and the examiner's answer (Paper No. 20, mailed February 20, 1997) for the examiner's complete reasoning in support of the rejections, and to the appellant's brief (Paper No. 19, filed January 22, 1997) for the appellant's arguments thereagainst.

OPINION

In reaching our decision in this appeal, we have given careful consideration to the appellant's specification and claims, to the applied prior art references, and to the respective positions articulated by the appellant and the examiner. Upon evaluation of all the evidence before us, it is our conclusion that the evidence adduced by the examiner is insufficient to establish obviousness with respect to any of the claims on appeal. Accordingly, we will not sustain the examiner's rejections under 35 U.S.C. § 103. Our reasoning for this determination follows.

Implicit in the above-noted rejections under 35 U.S.C. § 103 is the examiner's determination (final rejection, pp. 3-4) that Levy teaches or suggests all the claimed limitations of independent claim 3 except for the claimed fluid light guide means. The examiner then concluded that the claimed fluid light guide means was suggested by the teachings of Thomas.

The conclusion that the claimed subject matter is obvious must be supported by evidence, as shown by some objective teaching in the prior art or by knowledge generally available to one of ordinary skill in the art that would have led that individual to combine the relevant teachings of the references to arrive at **the claimed invention**. See In re Fine, 837 F.2d 1071, 1074, 5 USPQ2d 1596, 1598 (Fed. Cir. 1988).

Our review of Levy reveals that it fails to teach or suggest all the remaining claimed limitations of independent claim 3 except for the claimed fluid light guide means. Accordingly, even if the examiner's conclusion that the claimed fluid light guide means was suggested by the teachings of Thomas is correct, the combined teachings of the references would not have arrived

at the claimed invention. In that regard, Levy does not teach or suggest the following elements from independent claim 3:
(1) a catheter constructed and arranged for insertion into vessels, ducts, veins, arteries, or blood vessels of a living body, and (2) a supply of photocurable fluid soft tissue repair material.

The examiner believes that the above-noted elements are met by the device shown in Figure 2 of Levy. We do not agree.

The device shown in Figure 2 of Levy is used for treating mineralized body tissues, including a variety of dental tissues and bone. The device shown in Figure 2 of Levy includes an optical fiber 30 for conducting laser radiation to a region to be filled or coated, and two supply tubes 32 and 34 each connected to receive components of the coating or filling material from a respective supply unit 36 or 38. One example of a method carried out with the aid of the device shown in Figure 2 taught by Levy is where a mixture of materials, such as hydroxyapatite, ceramic and a dark colored material, e.g., carbon black, all in powdered form, is projected from tube 32 by being entrained in an air stream, while H_3PO_4 is projected from tube 34 by being entrained

in a second air stream. The two streams mix together in a region illuminated by reaction-producing laser radiation emanating from fiber 30 and react to form calcium phosphate. In addition, Levy discloses that depending on the ingredients of the mixture, the reaction product could be monobasic calcium phosphate, dibasic calcium phosphate, or tribasic calcium phosphate.

From our review of Levy, we find no teaching or suggestion that the device shown in Figure 2 of Levy is **constructed and arranged** for insertion into vessels, ducts, veins, arteries, or blood vessels of a living body. It is our view that the inherent size of Levy's device would be larger than that recited in claim 3. In addition, we find no teaching or suggestion that the device shown in Figure 2 of Levy has a supply of photocurable fluid soft tissue repair material. In that regard, it is our opinion that the none of the materials stored in Levy's supply units 36 and 38 are **photocurable fluid soft tissue repair material**.

We have also reviewed Thomas and Gottschalk applied in the rejections of the claims under appeal but find nothing therein which makes up for the deficiencies of Levy discussed above.

Accordingly, we cannot sustain the examiner's rejection of appealed claims 3 through 8 under 35 U.S.C. § 103.

New ground of rejection

Under the provisions of 37 CFR § 1.196(b), we enter the following new ground of rejection.

Claims 3 and 4 are rejected under 35 U.S.C. § 103 as being unpatentable over Sinofsky '670 or Sinofsky '677 in view of Thomas.

Sinofsky '670 discloses photoreactive suturing of biological materials for joining living tissues and promoting the healing of small biological structures. Figure 13 shows an apparatus 81 for remote application of sutures which can be incorporated into a catheter, endoscope or arthroscope and disposed adjacent to a remote anastomotic site. The apparatus 81 includes a suture port means 85 and a laser means 83. The suture port means 85 delivers a photoreactive suture material to the anastomotic site, the suture material comprising a structure with at least a portion of

the structure formed by a crosslinking agent such that upon irradiation of the suture material the crosslinking agent adheres to the biological material and thereby provides closure at the anastomotic site. The laser means 83 provides the necessary light energy in the form of laser radiation to effect crosslinking of the suture material at the anastomotic site. Sinofsky '670 teaches (column 2, lines 38-46) that various "biological glue" materials can be employed as crosslinking agents in either solid, liquid, gel or powder form to form a bond to tissue segments and thereby hold them together while natural healing processes occur. Examples of such crosslinking agents include collagen, elastin, fibrin, albumin and various other photoreactive polymeric materials. In addition, Sinofsky '670 (column 2, lines 60-65) uses the terms "anastomosis" and "anastomotic site" to broadly encompass the joinder of biological structures, including, for example, incision and wound healing, repair of blood vessels and other tubular structures, sealing of fissures, nerve repairs, reconstructive procedures, and the like.

Sinofsky '677 discloses endoscopic systems[3] for photoreactive suturing of biological materials for joining living tissues and promoting the healing of small biological structures. Figure 3 shows an endoscopic apparatus 81 for remote application of sutures. The apparatus 81 can be a catheter, arthroscope or other form of endoscope and disposed adjacent to a remote anastomotic site. The apparatus 81 includes a suture material delivery port 85 and a laser port 83. In Figure 4, an alternative embodiment is shown, simply consisting of a suture material delivery port 85 and a laser port 83 housed within a tubular casement 81. This instrument can be constructed small enough (e.g., less than about 2.0 micrometers) so that it can pass through a conventional endoscope instrument delivery channel. The suture port 85 delivers a photoreactive suture material 36 to the anastomotic site 30 where it can be draped across a fissure 32 or similar region requiring closure. The suture port can be equipped with a valve or wiper 69 to terminate or periodically stop the flow of suture material. The suture

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[3] Sinofsky '677 uses the terms "endoscope" and "endoscopic" to broadly encompass instruments such as laproscopes, cytoscopes, colonoscopes, sigmoidoscopes, arthroscopes, esophagoscopes, bronchoscopes, gastroscopes, thoracoscopes, peritoneoscopes, culdoscopes, **catheters** and the like (column 2, lines 62-66).

material comprises a structure with at least a portion of the structure formed by a crosslinking agent such that upon irradiation of the suture material the crosslinking agent adheres to the biological material and thereby provides closure at the anastomotic site. The laser means 83 provides the necessary light energy in the form of laser radiation to effect crosslinking of the suture material at the anastomotic site. Sinofsky '677 teaches (column 2, lines 52-61) that various "biological glue" materials can be employed as crosslinking agents in either solid, liquid, gel or powder form to form a bond to tissue segments and thereby hold them together while natural healing processes occur. Examples of such crosslinking agents include collagen, elastin, fibrin, albumin and various other photoreactive polymeric materials. In addition, Sinofsky '677 (column 3, lines 16-21) uses the terms "anastomosis" and "anastomotic site" to broadly encompass the joinder of biological structures, including, for example, incision and wound healing, repair of blood vessels and other tubular structures, sealing of fissures, nerve repairs, reconstructive procedures, and the like.

Thomas discloses at column 5, lines 21-23, that light rod 16 of his dental curing light gun could employ a liquid light guide.

After the scope and content of the prior art are determined, the differences between the prior art and the claims at issue are to be ascertained. Graham v. John Deere Co., 383 U.S. 1, 17-18, 148 USPQ 459, 467 (1966).

Based on our analysis and review of Sinofsky '670 and Sinofsky '677 and claims 3 and 4, it is our opinion that the only difference is the limitation that a fluid light guide means is positioned within the catheter relative to the optical fiber so as to direct the radiation emitted by the fiber toward the target site. In this regard, it is our opinion that the claimed supply of photocurable fluid soft tissue repair material reads on the crosslinking agents disclosed by both Sinofsky '670 and Sinofsky '677. In addition, it is our view that the apparatus 81 of Sinofsky '670 and the apparatus 81 of Sinofsky '677 are inherently constructed and arranged for insertion into vessels, ducts, veins, arteries, or blood vessels of a living body.

In applying the test for obviousness,[4] we reach the conclusion that it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the surgical instruments of either Sinofsky '670 or Sinofsky '677 to employ a liquid light guide as suggested and taught by Thomas for the self evident advantage of having the liquid act to guide the light to the anastomotic site.

CONCLUSION

To summarize, the decision of the examiner to reject claims 3 through 8 under 35 U.S.C. § 103 is reversed and a new rejection of claims 3 and 4 under 35 U.S.C. § 103 has been added pursuant to provisions of 37 CFR § 1.196(b).

This decision contains a new ground of rejection pursuant to 37 CFR § 1.196(b)(amended effective Dec. 1, 1997, by final rule notice, 62 Fed. Reg. 53131, 53197 (Oct. 10, 1997), 1203 Off. Gaz. Pat. Office 63, 122 (Oct. 21, 1997)). 37 CFR § 1.196(b) provides

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[4] The test for obviousness is what the combined teachings of the references would have suggested to one of ordinary skill in the art. See In re Young, 927 F.2d 588, 591, 18 USPQ2d 1089, 1091 (Fed. Cir. 1991) and In re Keller, 642 F.2d 413, 425, 208 USPQ 871, 881 (CCPA 1981).

that, "A new ground of rejection shall not be considered final for purposes of judicial review."

37 CFR § 1.196(b) also provides that the appellant, WITHIN TWO MONTHS FROM THE DATE OF THE DECISION, must exercise one of the following two options with respect to the new ground of rejection to avoid termination of proceedings (§ 1.197(c)) as to the rejected claims:

> (1) Submit an appropriate amendment of the claims so rejected or a showing of facts relating to the claims so rejected, or both, and have the matter reconsidered by the examiner, in which event the application will be remanded to the examiner. . . .
> (2) Request that the application be reheard under § 1.197(b) by the Board of Patent Appeals and Interferences upon the same record. . . .

No time period for taking any subsequent action in connection with this appeal may be extended under 37 CFR § 1.136(a).

REVERSED; 37 CFR § 1.196(b)

IAN A. CALVERT Administrative Patent Judge	)
NEAL E. ABRAMS Administrative Patent Judge	) BOARD OF PATENT APPEALS AND INTERFERENCES
JEFFREY V. NASE Administrative Patent Judge	)

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APPEAL NO. 97-2552 - JUDGE NASE
APPLICATION NO. 08/541,658

APJ NASE

APJ CALVERT

APJ ABRAMS

DECISION: **REVERSED;**
37 CFR § 1.196(b)

Prepared By: Delores A. Lowe

DRAFT TYPED: 14 May 98

FINAL TYPED: